BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

THIS PAGE BLANK (USPTO)

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : G01N 33/53, 33 /48 — A1

(11) International Publication Number: WO 00/04391

(43) International Publication Date: 27 January 2000 (27.01.00)

(21) International Application Number: PCT/GB99/02261

(22) International Filing Date: 14 July 1999 (14.07.99)

(30) Priority Data:
9815302.6 14 July 1998 (14.07.98) GB

(71) Applicant *(for all designated States except US)*: COZART BIOSCIENCE LIMITED [GB/GB]; 45 Milton Park, Abingdon, Oxfordshire OX14 4RU (GB).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: JONES, Osborn, Pierce [GB/GB]; Snowdonia Business Innovations Centre Limited, Park Menai, Bagnor, Gwynedd LL57 4BF (GB). SPIVEY, Robin, James [GB/GB]; Cozart Bioscience Limited, 45 Milton Park, Abingdon, Oxfordshire OX14 4RU (GB). HAND, Christopher, William [GB/GB]; Cozart Bioscience Limited, 45 Milton Park, Abingdon, Oxfordshire OX14 4RU (GB). BALDWIN, Dene [GB/GB]; Cozart Bioscience Limited, 45 Milton Park, Abingdon, Oxfordshire OX14 4RU (GB).

(74) Agent: ROBSON, Aidan, John; Reddie & Grose, 16 Theobalds Road, London WC1X 8PL (GB).

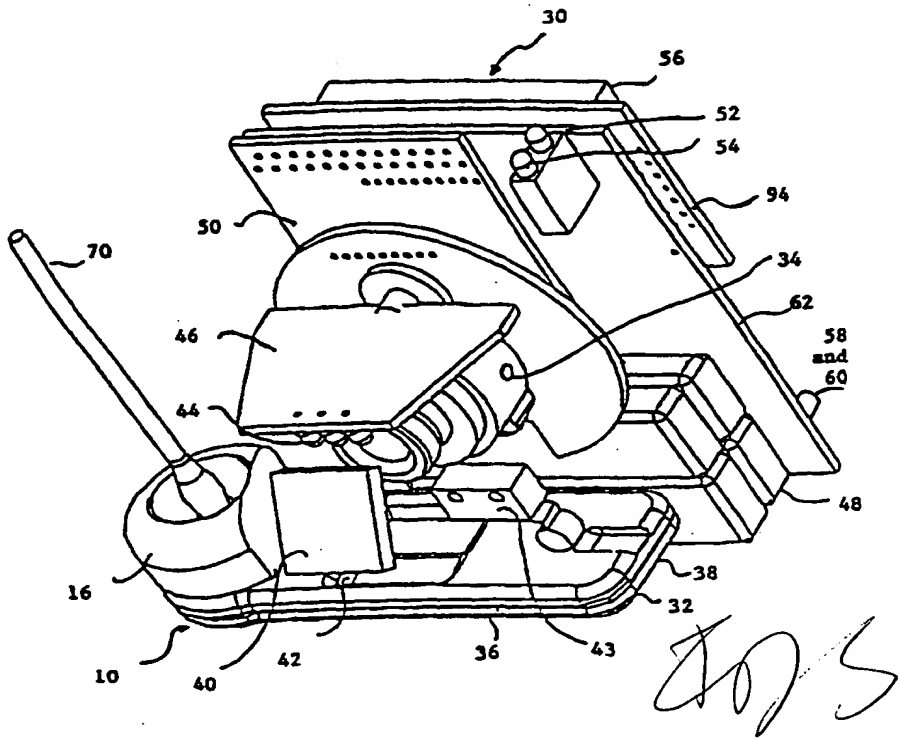
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: SCREENING DEVICE AND METHOD OF SCREENING AN IMMUNOASSAY TEST

(57) Abstract

Immunoassay tests run on samples of body fluid may be screened in the screening device and the lines formed by the immunoassay testing are interpreted to detect the presence of particular compounds such as drugs in the body. Light from an LED 44 is shone onto the window of an immunoassay test cartridge 10 illuminating a test membrane. Light reflected from the membrane 24 is reflected by a mirror 40 into the field of view of a charge coupled device 34. The image is digitised and outputted by video data interface to a CPU 80 for data processing. The digitised data is segmented according to preset data defining control regions test regions and background regions on the test membrane. The segmented data for the test region is compared to the data from the control region and the background regions to determine whether the test data exhibits any significant results compared to the control region and background regions. The results of the comparison are outputted to a liquid crystal display. The results may be displayed as either positive or negative for any particular substance or the concentration of the particular substance may be displayed. The screening device incorporates a timer which is activated when an immunoassay test cartridge is inserted into the device to ensure that an appropriate delay occurs to allow the immunoassay test to run correctly.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

SCREENING DEVICE AND METHOD OF SCREENING AN IMMUNOASSAY TEST

Background of the Invention

This invention relates to a screening device and a method of screening an immunoassay test. In particular the invention is applicable to a screening device for detecting the presence and concentration of particular drugs in a sample of saliva.

Samples of bodily fluid such as blood, sweat, urine and saliva may be used to detect the presence of particular compounds, such as drugs, in the body. Known methods of testing such samples for the presence of compounds include immunoassay "strip" testing where an antibody is labelled with a suitable marker, for example a visible marker such as colloidal gold, and drawn along a membrane passing over test regions and a control region impregnated with analyte conjugate substances or other binding substances. The presence of particular compounds in the sample are detected by a visible change occurring in the corresponding region due to the interaction of the labelled antibodies and the conjugate substances resulting in visible lines forming on the membrane in some of these regions. The colour formed may be proportional to or inversely proportional to analyte concentration depending on the assay format.

The interpretation of the lines formed by such immunoassay testing has previously been carried out subjectively by an operator comparing the intensity of the test line (or the absence or presence of a line) with that of a control, or reference, line.

Summary of the Invention

According to the present invention in a first aspect there is provided a screening device for interpreting the lines of an immunoassay test comprising:

illuminating means for illuminating an immunoassay test;

photosensitive detector means for detecting the intensity of light from the illuminating means which is reflected from the immunoassay test;

means, coupled to the output of the photosensitive detector means, for representing the intensity of the detected light by a data array;

memory means for storing preset data;

first data processing means, coupled to the memory means and to the output of the means for representing the intensity of the detected light by a data array, for segmenting the data array according to the preset data into control data, background data and test data;

second data processing means, coupled to the first data processing means, for determining whether the test data exhibits a statistically significant result; and

output means, coupled to the output of the second data processing means, for outputting the results from the second data processing means.

We have appreciated that in some fields of drug testing, for example in the use of a sample matrix other than urine such as saliva or blood, the amount of drug present in the sample may be very low, and the operator must be able to distinguish between a negative test corresponding to a complete absence of the drug in the sample and very low levels of drug present. This is difficult, requiring highly trained and skilled operators, and can prove unreliable when the levels of drugs are very low. For example, it is particularly difficult for an operator to distinguish

between levels of cannabis of 6ng/mL or lower by eye. If the test is to be run outside the laboratory, it is even more likely to be subject to inaccuracies which may be exacerbated by poor lighting conditions or by other environmental factors. We have, therefore, recognised the need for a portable drug tester which produces reliable and reproducible results.

We have also appreciated that a non-invasive test that can be conducted for example by the roadside would be beneficial. In a preferred embodiment of the invention we have therefore provided an automatic drug tester which can detect even very low levels of drugs from a saliva sample.

Advantageous features are set forth in the appendant claims. Preferably the screening device includes timing means. The timing means may delay the illumination of the immunoassay test until the immunoassay test has been allowed enough time to run. Preferably the screening device includes a display such a liquid crystal device to output the results to the screening device operator. Preferably the first and second processing means are provided by a single central processor unit and furthermore serial and parallel ports are provided from the central processor unit to allow the screening device to be controlled from an external processor and to allow the results to be downloaded from the screening device.

Preferably the immunoassay test is conducted on a disposable test cartridge using a saliva sample.

According to the present invention in a second aspect there is provided a method of screening an immunoassay test having discretely located test zones and a control zone interposed between background zones where the result of the test is indicated by the amount of a marker deposited in the control zones compared to the background and control zones, the

method comprising the steps of illuminating the immunoassay test, detecting the intensity of light reflected from the control zone, test zones and interposed background zones of the immunoassay test and converting the detected intensity to a data array, processing the data to determine whether the data shows a substance level above a threshold, and outputting the results of the processing.

According to the present invention in a third aspect, there is provided a screening device for interpreting the test zones of an immunoassay test comprising illuminating means for illuminating an immunoassay test, photosensitive detector means for detecting the intensity of light from the illuminating means reflected from the immunoassay test, means, coupled to the photosensitive detector means, for representing the intensity of the detected light by a data array, data processing means, coupled to the means for representing the intensity of the detected light by a data array, for determining whether the test zones of the immunoassay test exhibit statistically significant results; and output means, coupled to the data processing means, for outputting the results from the data processing means.

According to the present invention in a fourth aspect, there is provided a screening device for interpreting an immunoassay test comprising illumination means for illuminating the immunoassay test, means for detecting the intensity of the light from the illumination means which is reflected by the immunoassay test, timing means, for producing a delay before commencement of the interpretation of the immunoassay test, signal processing means, coupled to the timing means and coupled to the means for detecting the intensity of the light, for determining whether the immunoassay test shows statistically significant results after the delay has elapsed, and output means, coupled to the signal processing means, for outputting the results from the signal processing means.

Brief Description of the Drawings

A preferred embodiment of the invention will now be described in more detail, by way of example, with reference to the drawings in which:

Figure 1 is an isometric view of a test cartridge;

Figure 2 is a side view of an immunoassay test strip;

Figure 3 is an isometric view of a preferred screening device embodying the invention with a test swab and test cartridge located ready for analysis;

Figure 4 is a side view of the screening device, test cartridge and test swab of Figure 3;

Figure 5 is a block diagram of the electrical controls and electrical apparatus used in the screening device;

Figure 6 shows a graph of the typical variation of pixel intensity with pixel position for a single test and a single reference test; and

Figure 7 is a block diagram of the electrical controls and electrical apparatus which may alternatively or additionally be used in the screening device.

Detailed Description of the Preferred Embodiment

Figure 1 shows a test cartridge 10 used to run the immunoassay tests to be screened by the screening device. The test cartridge 10 may be disposable and is formed from a top 12 and a base 14. The top 12 of the test cartridge 10 has a cylindrical swab holder 16 extending vertically from

one of the shorter ends of an elongate tray 18. The swab holder 16 is open at both ends.

Ridges 20 extend upwardly from both of the longer sides of the elongate tray along the length of the tray. A rectangular window 22 extends transversely between the ridges 20 across the elongate tray and extends over a longitudinal length of the elongate tray which is less than the overall length of the elongate tray such that the window 22 is bounded on all four sides by the elongate tray 18. The window 22 extends through the entire thickness of the elongate tray 18.

Figure 2 shows an immunoassay test strip 23. The upper surface of a flat, elongate nitrocellulose membrane 24 is bonded to a waste pad 28 at one end and to a conjugate release pad 27 at its other end. Both the conjugate release pad 27 and the waste pad 28 overlap the ends of the nitrocellulose membrane 24. The other end of the conjugate release pad 27 overlaps an absorbent sample pad 26 and is bonded at its upper surface to the lower surface of the absorbent sample pad 26. When fluid is applied to the sample pad 26 it is drawn along the sample pad by capillary action, through the conjugate release pad 27 and nitrocellulose membrane 24 and surplus fluid is absorbed by the waste pad 28.

The base 14 of the test cartridge 10 has a rectangular portion with a rounded portion at one end. An immunoassay test strip 23 is laid onto the upper surface of the base 14 with the sample pad 26 located in the rounded portion of the base 14. The immunoassay strip 23 (shown in dashed lines on Figure 1) extends longitudinally along the length of the base 14 from the end of the base furthest from the rounded portion stopping within the rounded portion but short of the end of the rounded portion. The top 12 is then assembled onto the base 14 by fitting the cylindrical swab holder 16

onto the rounded portion of the base 14 and the elongate tray 18 of the top 12 onto the rectangular portion of the base 14. The top 12 and base 14 are joined for example by gluing. Alternatively, the top 12 may be designed to snap-fit onto the base 14. The top 12 may be made of a single unit so that the elongate tray 18 and the swab holder 16 are a single piece.

The conjugate release pad 27 holds a mobile and visible label, or marker, such as colloidal gold, and is in contact with the nitro-cellulose membrane 24 such that when fluid is added to the swab holder 16, it is drawn by capillary action downstream from the swab holder 16 through the absorbent sample pad 26 through the conjugate release pad 27 and subsequently through the nitro-cellulose membrane 24. The use of cartridges of this type is known in the prior art for example from EP 0291 194 by Unilever NV titled "Immunoassays and devices therefor".

At discrete intervals along the nitro-cellulose membrane 24 drug-protein derivatives are biochemically bound to the nitro-cellulose membrane, producing an immobile zone of drug-protein derivative which spans the width of the nitro-cellulose membrane. Towards the extreme downstream end of the nitro-cellulose member, downstream of all the immobile drug-protein derivative zones, is a control zone which also spans the width of the nitro-cellulose membrane. The test zones and control zone are interposed between background zones where the nitrocellulose membrane 24 does not have bound drug conjugate but has been blocked by other protein or other substances to prevent non-specific binding. Antibodies to each drug which is to be tested for, conjugated with colloidal gold, are placed on the conjugate release pad 27. When saliva is transferred from the swab in the presence of a run-fluid, the resulting sample passes across the absorbent sample pad 26 and across the conjugate release pad 27 where it mixes with the antibody-gold

conjugates. The sample then travels the length of the nitro-cellulose membrane 24.

If the particular drug is present in the sample it will bind to the antibody-gold conjugate. When the bound drug subsequently passes over the specific drug-protein derivative the antibody-gold conjugate has already been bound to the drug in the sample and is not free to bind with the drug-protein derivative bonded to the membrane. If the particular drug is absent from the sample, the antibody-gold conjugate will be free to bind to the drug-protein conjugate causing the antibody-gold conjugate to become immobilised at the site of the drug-protein conjugate. The visible marker is deposited in the test zone as a coloured line or stripe. In between these two extremes some of the antibody-gold conjugate will bind with the drug-protein derivatives on the strip creating an intermediate intensity of colour. The intensity of the colour on the particular drug-protein zone is therefore inversely proportional to the amount of drug present in the sample.

The depth of colour of the control zone should always be significant and the control zone is designed with this in mind. The colour of the control zone can then be used to indicate that the test has been successfully run and to threshold colour levels in specific drug conjugate zones.

Figure 3 shows the test cartridge 10 of Figure 1 located into the screening device 30. The screening device 30 includes a receiving section, an imaging section and a display section. The receiving section is located at the rear of the screening device and receives and aligns a test cartridge prior to the screening operation. The imaging section is located centrally in the screening device between the receiving section and the display section and includes the illuminating and imaging equipment, the processing capabilities and battery pack. At the front of the

screening device is the display section for outputting the results of the screening operation. A cover (not shown) which is open at the front end of the screening device 30 encases the remaining five sides of the screening device 30. A facia cover (not shown) is attached to the cover to completely encase the screening device 30, protecting the screening device and the user from accidental damage.

The receiving section includes a receiving bracket 32 and a microswitch 43 and also positions and supports a half silvered mirror 40 which forms part of the imaging section. The receiving bracket 32 has a back 38 and two parallel arms 36. The back 38 is connected at either end to one end of each arm forming a U-shaped bracket. The open end of the U-shaped receiving bracket 32 is directed outwardly from the screening device 30 and is aligned with an opening in one side of the cover (not shown) towards the rear of the screening device 30. The opening is large enough to allow a test cartridge 10 to be inserted into the screening device 30. The arms of the receiving bracket 32 are spaced apart by a distance equal to the width of the test cartridge 10 and have the same longitudinal length as that of the elongate tray 18 of the test cartridge 10. The arms 36 have a C-shaped cross-section. When a test cartridge is inserted into the opening the ridges 20 on the test cartridge 10 mesh with the C-shaped cross-section of the arms 36 of the receiving bracket 32 to direct the test cartridge into the screening device 30. The test cartridge 10 is inserted into the screening device 30 until the end of the test cartridge reaches the back of the receiving bracket when pressure against further insertion will be felt.

A half silvered mirror 40, which forms part of the imaging section of the screening device, is supported above the window 22 of the test cartridge 10 by a column 42 extending upwardly from the arm 36 of the receiving bracket 32 nearest the rear of the screening device 30.

A test swab 70, holding a saliva sample, is located in the swab holder 16 of a disposable test cartridge 10. The test cartridge 10 is inserted into the screening device 30 by the end furthest from the swab holder 16 and is positively located in the correct screening position by receiving bracket 32. The back 38 of the receiving bracket 32 prevents the test cartridge 10 from being inserted too far into the screening device 30 and ensures that the window 22 of the cartridge 10 is located directly in front of and beneath the CCD 34 of the screening device 30. Electrical circuitry 50 controlling the operation of the screening device including operation of the CCD 34 are housed within the screening device 30 towards the front of the screening device 30 in front of the CCD 34, test cartridge 10, and rechargeable batteries 48.

A microswitch 43 is supported above the test cartridge 10 from the arm 36 of the receiving bracket 32 nearest the CCD 34. When a test cartridge 10 is inserted into the screening device 30 the microswitch 43 is displaced vertically causing an electrical signal to be emitted from the microswitch to signal that the correct insertion of a test cartridge 10 has been detected. During screening of the test cartridge 10, the microswitch 43 may resist any displacement of the test cartridge 10 once it has been fully inserted into the screening device.

The imaging section includes illuminating means, photosensitive detector means, means for representing the intensity of the detected light by a data array, data processing means for segmenting the data and comparing the segmented data and output means. The illuminating means is provided by three light emitting devices (LEDs) 44 which are mounted in a horizontal line parallel to the longitudinal length of the test cartridge 10 with the middle LED centred vertically above the centre of window 22 of the test cartridge 10. The photosensitive detector means and means

for representing the intensity of the detected light by a data array are provided by a CCD 34 which includes an imager 82, a video digitiser 84 and a video data interface 86 (shown on Figure 5). Alternatively, the photosensitive detector means may be made up from a CCD array device together with a control and data conversion interface. The imager of the CCD 34 is directed towards the rear of the screening device 30. A mounting plate 46 is attached to the upper body of the CCD 34 towards the front of the screening device 30. The mounting plate 46 extends horizontally from the body of the CCD 34 towards the rear of the screening device 30 and finished directly above the window 22 of the test cartridge 10. Three LEDs 44 are attached in a row at the front of the underside of the mounting plate 46. When illuminated, the light from the LEDs 44 shines directly onto the window 22 of the test cartridge 10. The mirror 40 is inclined from the vertical by approximately 35° such that the window 22 of the test cartridge is reflected into the field of view of the CCD 34. Light reflected from the immunoassay test is detected by an array of photosensitive detectors in the imager 82. The photosensitive detectors emit an electrical signal proportional to the intensity of light detected. The video digitiser 84 scans each of the photosensitive detectors in turn, converting the analogue data to digital data and storing the data in an array. The array of digital data is subsequently outputted to a central processor unit (CPU) 80 via the video data interface 86.

Rechargeable batteries 48 supply power to the CCD 34, LEDs 44, microswitch 43 and electrical circuitry 50. The rechargeable batteries 48 towards the front of the imaging section below the CCD 34. The electrical circuitry 50 which forms the final part of the imaging section is described later with reference to Figure 4 and Figure 7.

At the front of the screening device 30 is the display section including two test indicator LEDs 52 and 54, a

liquid crystal device (LCD) 56, operating buttons 58 and 60 and a front plate 62. The front plate 62 is slightly smaller than the facia cover and is located at the front of the screening device 30 directly behind the facia cover. The two test indicator LEDs 52 and 54 are mounted at the top of the rear of the front plate with the LEDs 52 and 54 protruding above the level of the front plate 62. Holes in the top of the cover at its front corner allow the test indicator LEDs 52 and 54 to protrude through the cover such that they are visible on top of the device.

An LCD 56 and its associated backlight driver 94 are mounted at the top of the front plate 62 between the front plate 62 and the facia cover. The facia cover has a window through which the LCD 56 is visible but which obscures the backlight driver 94, located behind the LCD 56, from view. Also mounted onto the front plate 62 between the facia cover and the front plate are two operating buttons 58 and 60. The facia cover has holes in corresponding locations to allow the user to operate the buttons 58 and 60 through the facia cover.

Additionally holes for an infra-red communication port and a serial and parallel link for connecting the screening device to a personal computer (PC) may be provided in the cover and corresponding connections from the electrical circuitry 50 may be provided.

Figure 4 shows a partially sectioned side view of the screening device of Figure 3.

Figure 5 shows a block diagram of the electrical components of the screening device 30. The screening device 30 is based around a microprocessor or central processor unit (CPU) 30 and the CCD 34. The CCD 34 comprises an imager 82, and associated video digitiser 84 and video data interface 86. The screening device may also includes a keypad 88 or

may be operated via a combination of buttons provided on the facia. The screening device also includes electrically erasable read only memory (EEPROM) 90, dynamic random access memory (RAM) 92 and the liquid crystal display (LCD) 56. The EEPROM 90, RAM 92 and LCD 56 are connected to the CPU 80. Alternatively, the EEPROM and RAM may be internal to the CPU. The LCD 56 may be backlit and control is provided via a backlight driver 94 which is connected to both the CPU 80 and the LCD 56.

The keypad 88 may be used to allow a user to enter data required by the CPU 80 to control operation of the screening device. Results from the screening device 30 are displayed to the user via the LCD 56 which also acts to prompt the user for the data required to operate the screening device. Power is supplied to the CPU 80, LEDs 44, LEDs 58 and 60, microswitch 43 and CCD 34 from a rechargeable battery pack 48. The batteries can be recharged from the mains supply or, for example from a car cigarette lighter, via an adaptor. The operation of recharging the batteries can be controlled by the CPU or alternatively can be controlled manually. Preferably, the screening device automatically shuts down to preserve battery life if no cartridge is present or if the results of the previous screening have been displayed for longer than a preset time, say 5 minutes. Preferably, if an external power supply is detected by the screening device the CPU 80 automatically commences a battery recharging program. Preferably, the batteries can hold enough charge to operate continuously for up to 24 hours without being recharged.

The CPU 80 controls an electroluminescent backlight driver 94 to backlight the LCD 56. Preferably, the LCD 56 is capable of displaying two rows each of 8 alphanumeric characters. In addition to the LCD display, two LEDs, one red 58 and one green 60, are provided. Illumination of the LEDs 58 and 60 is controlled by the CPU 80 and may be used

to indicate visually the progress and status of the scan, ie in progress, results ready for display, or the outcome of the test. Alternatively, the progress or results could be indicated by an audible signal. The LCD 56 may also display status information.

In the embodiment described above the overall size of the device is approximately 85mm by 80mm by 65mm and the device weighs approximately 300g. The CCD 34 may be, for example, a Connectix Quickcam, incorporating a CCD imager, video digitiser and video data interface.

Operation of the screening device will now be described. Disposable saliva test swabs 70 are stored in a sealed pack and one swab removed immediately prior to use. The swab should be removed from the pack by the person whose saliva is to be tested and is wiped under the tongue for approximately 15 seconds. The swab 70 is then inserted into the swab holder 16 of a disposable test cartridge 10. Ten drops of a run fluid, which may be of any conventional type, are added to the swab holder 16. The run fluid transports the sample of saliva from the test swab 70 to the absorbent pad 26 and onto the conjugate release pad 27, where the saliva and run fluid mixture mixes with the labelled (e.g. with gold, coloured latex particles carbon particles, fluorescents, or any other suitable label) anti-drug antibodies. The sample subsequently travels along the length of the nitro-cellulose membrane 24. At each test zone any unbound labelled drug antibodies are bound to the drug-protein derivative of the test zone. Any of the labelled antibodies which have not been bound to the test zones passes over the control zone where it becomes bound to the control zone. The result is a number of lines of varying intensity spanning the width of the membrane at points along the length of the nitro-cellulose membrane corresponding to the drug-protein derivative zones and the control zone. Each drug-protein derivative zone can be used

to detect a different drug. The higher the concentration of the particular drug in the saliva sample, the less intense the colour in that drug-protein derivative zone.

As soon as the test swab 70 has been located in the swab holder 16 the test cartridge 10 is inserted into the screening device by gently pushing the end of the cartridge furthest from the swab holder 16 into the opening of the screening device 30, allowing the test cartridge 10 to be guided by the receiving bracket 32. The test cartridge 10 should be inserted gently until the end of the test cartridge furthest from the swab holder 16 reaches the back 38 of the receiving bracket 32 when there will be resistance against further insertion.

Once inserted into the screening device the cartridge is left in position until the scanning process has been completed. A message on the LCD and/or flashing of the LEDs indicates that the scan is complete. Only then may the cartridge be removed.

As the test cartridge 10 is pushed into position it displaces the micro switch 43. A signal is sent from the microswitch 43 to the CPU 80 which activates the scanning process by down-loading a preset program from EEPROM 90. Timer means are provided to delay illumination of the immunoassay test until the test has had time to run. Once the presence of a test has been detected the CPU 80 commences initialisation by prompting the user to set a timer to alert the operator to wait a sufficient time for the sample to travel the length of the membrane. Alternatively the user may time the test manually and an on/off power switch can be provided which the user can operate once the test has been run and the test cartridge 10 has been inserted into the screening device 30. The timer function may be provided by a separate timer integrated circuit controlled by the CPU 80 or may alternatively be

provided internally to the CPU 80. When the prerequisite length of time has elapsed, which is generally of the order of five minutes, the timer sends a signal to the CPU 80 which alerts the operator that the sample is ready for screening for example by flashing LEDs 58 and 60, displaying a message on LCD 56 or sounding an alarm. The screening device is also able to time the test, analyse results, output results and store the results automatically.

A plurality of adjacent membranes may be incorporated into a single test cartridge with the membranes running longitudinally the entire length of the cartridge from the absorbent pad to the end of the cartridge furthest from the swab holder and each membrane 24 having a transverse width less than that of the test cartridge 10 such that a plurality of membranes, for example two, may be placed side by side in the test cartridge 10. Processing the results of the saliva test depends on identifying the intensity of the lines on each membrane and relating each line to the drug which is the subject of that particular test. Details of the number of adjacent membranes in the particular cartridge and the number, type and position of the drug-protein derivative zones and control zone on each membrane are required for processing of the results. These details can be held in the EEPROM and accessed by the CPU 80 upon detection and recognition of the cartridge type or the user can directly enter data required for the CPU 80 to recognise the test cartridge 10. If the test cartridge 10 is to be recognised by the CPU 80 it may carry appropriate marking such as a bar code, which is read by appropriate means provided in the screening device and the information is passed to the CPU 80.

The test cartridge 10 may be printed with the name of the test which may be automatically read and identified by the CPU 80. The test cartridge 10 may also contain an implanted microelectronic circuit which may be interrogated by the CPU

80 by means of electrical, infra-red or inductive links in order to ascertain whether the cartridge is acceptable and to determine the nature of the test.

The CPU 80 enables the CCD 34 and switches on the appropriate LED 44, thus illuminating the window 22 of the test cartridge 10. In the presently preferred embodiment three LEDs are provided, with wavelengths of 430nm, 565nm and 660nm respectively. The wavelength of light emitted by each LED is chosen with reference to the characteristics of the label, in particular to its colour. Preferably the wavelength of the light used to illuminate the immunoassay strip is complementary to the wavelength of the particular label in order to provide the best contrast. In the presently preferred embodiment, colloidal gold is employed as the label and as colloidal gold is pink in colour a green LED with a wavelength of 565nm is used. Whilst the label has been described as visible and the example of colloidal gold as a label would be visible to the human eye, the label may be chosen to be visible to the CCD array under certain lighting conditions and may not, either under normal lighting conditions or under special lighting conditions, be visible to the human eye.

Light from the LED 44 shines onto the window 22 of the test cartridge 10 illuminating the nitro-cellulose membrane 24 visible through the window 22. The illuminated membrane 24 is reflected by the mirror 40 into the field of view of CCD 34. The image is digitised and outputted via a video data interface to the CPU 80 for data processing. Preferably, the digital data is stored to dynamic RAM for subsequent processing.

The image captured by the CCD 34 is skewed by the reflection from the mirror 40 and the CPU 80 must first apply an algorithm to correctly align the digitised data for processing. Preferably, the CPU 80 runs an initial

correction algorithm to arrange the data for subsequent processing. Preferably the initial correction algorithm is set when the device is manufactured and, if necessary, calibrated, at points during the life of the device rather than at the beginning of each test.

Each cartridge may be used to run tests for a number of different drugs. This can be achieved either by using a single membrane with a larger number of drug-protein derivative zones or using a number of membranes in a single cartridge. Up to eight or more drugs may be analysed at any one time using a combination of these methods. In the presently preferred embodiment, drug-protein derivatives for cannabis (THC), cocaine (COC), opiates (OPI), methadone, ecstasy and amphetamines (XTC) and benzodiazepines (BZO) are bound to the nitro-cellulose membrane at discrete intervals. The results for each of these drugs tests is indicated separately by the screening device. Two panel tests, for example for methadone and opiates, may also be provided. The data must then be segmented such that each segment relates to one membrane only. The separate segments are then processed separately. In the presently preferred embodiment the CCD array is a Texas TC 255 P CCD array which is made up of 324 x 240 elements. The digital data must be segmented to correspond to the 344 x 240/N pixels covering that particular membrane only where N is the number of membranes in the cartridge.

Each membrane is therefore represented by an array of p x q pixels where the p pixels span the length of the membrane and the q pixels span the width of the membrane. The drug-protein derivatives are bonded across the entire width of the membrane at discrete intervals along the membrane. At any location (p,r) where p falls within a particular drug-protein derivative zone the intensity of the pixel is related to the amount of that particular drug in the sample, regardless of the value of r in the range $0 \leq r \leq q$. The

intensities of the pixels at (p,r) are therefore summed over the range $0 \leq r \leq q$ for each p.

Slight discrepancies between the theoretical position of the membrane and the actual position of the membrane may be accommodated by the screening device. The CPU 80 compares the summed intensity at a specific location corresponding to the theoretical centre position of the control zone with the intensity at a predetermined number of adjacent locations to determine whether there is any discrepancy between the theoretical location of the control zone with the actual location of the control zone. The CPU 80 applies a corresponding offset to subsequent calculations if the theoretical and actual locations of the centre of the control zone differ. The offset must be determined by reference to the control zone because if any of the tests are positive then the intensity of that drug-derivative zone will be correspondingly reduced.

Alternatively, or in addition, the test strip 23 and test cartridge 10 may be of contrasting colours. The unskewed data may be processed using the contrast between the test cartridge 10 and the test strip 23 to determine the actual location of the centre of the test strip which may then be used to apply an offset to the data if required.

Figure 6 shows a typical graph of the resulting pixel intensity against the location of the pixel for a single protein-drug derivative zone and a single control, or reference, zone. Once any offset of the membrane from the theoretical position has been identified, the data is segmented according to whether it lies in a drug-protein derivative zone, the control zone or in a space between adjacent zones as shown in Figure 6. Preferably, the CPU 80 is a Hitachi H8/3002 microprocessor chip but any other suitable microprocessor chip may be used. The CPU 80 segments the data into a first plurality of data

corresponding to the control zone, a second plurality of data corresponding to the test zones, and a third plurality of data corresponding to the background zones. The CPU 80 then processes the first, second and third pluralities of data, performing the following calculations to determine whether each drug is present in the sample.

Define

$$RW1 = \sum_{p1}^{p2} \qquad RB = \sum_{p2}^{p3} \qquad RW2 = \sum_{p3}^{p4}$$

and

$$TW1 = \sum_{p5}^{p6} \qquad TB = \sum_{p6}^{p7} \qquad TW2 = \sum_{p7}^{p8}$$

Then estimate

$$REF = 1 - \left(\frac{2RB}{(P3 - P2 + 1)(RW1 + RW2)} \right)$$

and

$$TEST = 1 - \left(\frac{2TB}{(P7 - P6 + 1)(TW1 + TW2)} \right)$$

If REF≤0 then the reference, or control, zone has not bound any of the products present in the saliva sample and run fluid after it passed over the drug-protein derivative zones. Either the control zone is faulty on the membrane or the test has not been completed correctly which may be due to an insufficient amount of run-fluid being added to the swab holder. The screening device will display an error

message and the cartridge should be removed, reinserted and reread or disposed of and another cartridge run. However, the delay for the test to be performed is not required in these circumstances and the operator is provided with a means for bypassing the timer operation to commence immediate image acquisition and data processing. If an error is still detected then the test must be re-run using a new cartridge and saliva sample.

If REF>0 showing that the test has been successfully completed but TEST≤0 then the drug concentration in the sample is such that all the antibody-gold conjugates have been bound to the drug in the sample. The results of that test is set to 100%. The test is assigned a qualitative level "Positive". A quantitative value would be represented as "greater than" a certain level.

If TEST>0 and REF>0 then the test band concentration is determined as follows:

$$TEST\ BAND\ CONCENTRATION = 1 - \left(\frac{TEST}{REF} \right)$$

The percentage of drug present in the sample is given by 100xTest Band concentration %.

The results for the concentration of each drug can be displayed in a number of ways. The LCD 56 may be used to display the name of the drug and its result. Alternatively only the fact that the test for that particular drug is positive may be displayed. If the display is to indicate a positive or negative result only then the CPU 80 must have access to a threshold for each drug which could be held in the EEPROM. For each drug if the detected concentration exceeds the threshold then the result would be positive and if the detected concentration falls below the threshold then

the result would be negative. Each separate drug-protein zone must be tested in this way with reference to the control zone to determine the concentration of that drug in the saliva sample.

Alternatively, or in addition, positive and negative results could be displayed using combinations of the LEDs 52 and 54 provided on the top of the screening device. In the presently preferred embodiment, the red LED 52 will be continuously illuminated and the green LED 54 intermittently illuminated to indicate that the particular drug test is positive, and the green LED 54 will be continuously illuminated with the red LED 52 flashing if the drugs test is entirely negative. The operator may step through the result of each individual drug test by operating the buttons 58 and 60 on the front of the screening device or may view all the results simultaneously by down loading the results to a pc with the necessary graphics facilities. Results may be stored within the screening device until they are down-loaded to a PC. The test image may be stored for subsequent downloading to a PC.

If the test indicates that any of the drugs are present in the sample, follow up testing using an alternative test method may be performed.

The CPU 80 is provided with a programming interface 98 to allow the screening device to be programmed for example from a remote PC. Serial and parallel PC links 96 and/or an infra-red link may provided from the CPU 80 allowing the control of the screening device to be relinquished to a pc or mainframe computer. Results of the testing can also be displayed by the pc having been down loaded from the screening device. Preferably, the CPU 80 is capable of running self-testing diagnostic routines stored in EEPROM at intervals which may be controlled either by presets in the CPU or may be initiated on demand by the user.

In certain situations it may be preferable for the screening device operator to be provided with a display indicating the image produced by the CCD 34. An interface for the CCD 34 may be provided to allow the operator to view the image on a small graphics panel.

It may also be preferable to provide means for storing the image of the person who provided the test sample. For this purpose, the mirror 40 could be adjusted between the test screening position and a second position which allowed the image of the person being tested to be reflected onto the imaging means for storage and subsequent retrieval. Additional optical apparatus, for example a lens, may be required to modify the focal length along the external light path.

Figure 7 shows a block diagram of the electrical controls and electrical apparatus which may also be used in the screening device. Apparatus and controls which correspond to those of figure 4 are given the same reference numerals and reference should be made to the description above.

In particular, a CMOS image sensor 82' may be used instead of a CCD image sensor. A driver is associated with the CMOS image sensor 82' and interfaces between the CPU 80 and CMOS image sensor 34'. A video buffer 86' replaces the video data interface 86 of figure 5. Preferably, a Vision VV5404 imaging device having a resolution of 356 x 292 pixels is used.

The electroluminescent backlight driver 94 shown in figure 5 may also be replaced by light emitting diode backlight driver 94'. Furthermore, the volatile memory device 90 provided by an EEPROM in the apparatus of figure 5 may be replaced by FLASH memory and/or the non-volatile memory provided by the dynamic RAM (DRAM) in figure 5 may be replaced by static RAM (SRAM). An LCD 56' with a higher

resolution capable of handling graphics of 100 x 64 pixels may also replace the LCD 56 of figure 5. This would allow all the test results to be displayed simultaneously if required. Batteries which are capable of holding sufficient charge to power the screening device for up to 20 days may be provided.

Preferably, means 45 for adjusting the intensity of each of the LEDs 44 may be provided. Adjustable current LED drivers may be used as shown in figure 7.

The half silvered mirror 40 of figures 3 and 4 may be replaced by a plain first surface mirror 40. The angle of the mirror and the imaging device may be altered to reduce the skew of the image. For example, by adjusting the angle of the mirror 40 to 55° to the vertical and using a CMOS image sensor inclined at 10° to the vertical, the combined inclination of the CMOS image sensor 82' and the mirror 40 minimises the difference in the image width over the width of the test strip with the result that the image captured by the CMOS image sensor 82' is substantially unskewed relative to the actual immunoassay test strip 23. In the case that the image captured by the imaging device is unskewed, the CPU 80 is not required to apply an algorithm to correct the digitised data prior to processing the data.

Different numbers of LEDs 44 may be used to illuminate the test strip 23. For example, four LEDs rather than three may be mounted in a horizontal row parallel to the longitudinal length of the test cartridge. If four LEDs are used, the two outermost LEDs may be chosen to emit light of one wavelength whilst the two innermost LEDs may be chosen to emit light of a different wavelength. With this configuration, only one pair of LEDs may be used to illuminate the immunoassay test strip 23 for the purpose of determining the drug concentration. The remaining pair of LEDs may be used for non-disruptive messaging, for example

reading a bar code on the test strip or cartridge. The intensities of the LED pairs may be matched to provide optimal illumination of the immunoassay test strip 23. Suitable wavelengths for the LED pairs are 566nm and 639nm. However, the primary requirement in choosing suitable LEDs is that the wavelength of light emitted is compatible with the marker used on the immunoassay test strip 23 and that illumination of any messaging markings does not corrupt the test results.

The size and weight of the screening device may be affected by the choice of electrical apparatus and controls. Using a Vision VV5404, the overall dimensions and weight of the screening device may be 210 x 70 x 50mm and approximately 240g.

The control band may only be used to verify that the test has run successfully and may not be used for the quantification of individual drug concentration calculations. In this case, null data may be provided in order to quantify the test results. Such null data may, for example, correspond to the data which would be generated by illuminating a blank immunoassay test strip under identical conditions to the illumination of the experimental immunoassay test strip. Such null data would then give an estimate of the intensity observed when the concentration of a drug in the sample under test approximates or exceeds the amount of conjugated antibodies released from the relevant pad. Such null data may be compared to the test data to determine the concentration of the substance in the sample under test.

Null data may be approximated by suitable filtering of the experimental data eliminating any need for separate illumination of an unused, clean test strip as a reference strip. For example, data corresponding to the length and width of one of the background zones may be interpolated to

produce an estimate of the intensity that is representative of null data. Prior to interpolation, the data may be smoothed to improve the null data. More sophisticated filtering techniques, including adaptive filtering, may also be used in estimating the null data. Once null data has been estimated or provided, the test data and null data may therefore be compared to determine the concentration of the substances in the test zones.

For use in adverse weather conditions, various adaptations (not shown in figure 1) to the test cartridge may be provided. A retractable, transparent cover may be provided on the test cartridge to protect the immunoassay test strip 23 which is otherwise exposed through the window 22, for example from exposure to rain. The window is retracted automatically upon insertion of the test cartridge into the screening device and is redeployed when the test cartridge is removed from the screening device. The run fluid may be contained within the cylindrical swab holder 16 of the test cartridge 10 and held in place by a thin penetrable membrane that is pierced by introduction of a test swab into the swab holder 16. A second, elastic membrane with an aperture may be positioned above the run fluid membrane in the cylindrical swab holder 16. The aperture of the elastic membrane expands to allow a test swab to be inserted through the aperture and would form a waterproof seal around the test swab 70 prior to the test swab piercing the run fluid membrane. Upon removal of the test swab 70, the aperture of the elastic membrane contracts preventing fluid, other than that on the test swab, from entering the test cartridge.

With respect to the above description, it is to be realized that equivalent apparatus and methods are deemed readily apparent to one skilled in the art, and all equivalent apparatus and methods to those illustrated in the drawings and described in the specification are intended to be encompassed by the present invention. Therefore, the

foregoing is considered as illustrative only of the principles of the invention. Further, since numerous modifications and changes will readily occur to those skilled in the art, it is not desired to limit the invention to the exact construction and operation shown and described, and accordingly, all suitable modifications and equivalents may be resorted to, falling within the scope of the invention.

For example, in alternative embodiments of the invention, the sample to be tested could include urine, serum, plasma, ocular fluid or filtered whole blood. Suitable filtering systems for whole blood could be incorporated into the cartridge. The screening device could also used in other areas of immunodiagnostics. For example, the screening device could be used to analyse the concentration of tumour markers in the blood samples of patients undergoing treatment for cancer. The screening device could also be adapted for use to measure the levels of hormone, or therapeutic drug present in a sample or to test for bacteria, viruses or other microorganisms present in a variety of sample types. Alternatively the screening device could be adapted to screen samples for allergies.

It should be noted that the features described by reference to particular figures and at different points of the description may be used in combinations other than those particularly described or shown. All such modifications are encompassed within the scope of the invention as set forth in the following claims.

C L A I M S :

1. A screening device for interpreting the lines of an immunoassay test comprising:

illuminating means for illuminating an immunoassay test;

photosensitive detector means for detecting the intensity of light from the illuminating means which is reflected from the immunoassay test;

means, coupled to the output of the photosensitive detector means, for representing the intensity of the detected light by a data array;

memory means for storing preset data;

first data processing means, coupled to the memory means and to the output of the means for representing the intensity of the detected light by a data array, for segmenting the data array according to the preset data into control data, background data and test data;

second data processing means, coupled to the first data processing means, for determining whether the test data exhibits a statistically significant result; and

output means, coupled to the output of the second data processing means, for outputting the results from the second data processing means.

2. A screening device according to claim 1, wherein the second data processing means compares the control data, background data and test data to determine whether the test data exhibits a statistically significant result compared to the control data and background data.

3. A screening device according to claim 1, wherein the second data processing means is coupled to means for providing null data, the null data being representative of the intensity of light reflected from the background areas

between the lines, the second data processing means comparing the test data and the null data to determine whether the test data exhibits a statistically significant result.

4. A screening device according to claim 1, wherein timing means are provided for delaying the illumination of the immunoassay test until the immunoassay test has been completed.

5. A screening device according to claim 1, wherein the first and second data processing means are provided by a central processor unit.

6. A screening device according to claim 5, wherein serial and parallel ports are provided from the central processor unit to allow the screening device to be controlled from an external processor or to allow the screening device to download the results of the comparison of the control data, background data and test data.

7. A screening device according to claim 1, wherein the photosensitive detector means and the means for representing the intensity of the detected light by a data array are provided by a charge coupled device and associated video digitiser and video data interface.

8. A screening device according to claim 1, wherein the photosensitive detector means and the means for representing the intensity of the detected light by a data array are provided by a CMOS imaging sensor and associated driver and video buffer.

9. A screening device according to claim 1, wherein the output means are display means.

10. A screening device according to claim 1, wherein the immunoassay test is conducted on a saliva sample.

11. A screening device according to claim 1, wherein the immunoassay test is performed in a disposable test cartridge.

12. A screening device for interpreting the test zones of an immunoassay test comprising:

illuminating means for illuminating an immunoassay test;

photosensitive detector means for detecting the intensity of light from the illuminating means reflected from the immunoassay test;

means, coupled to the photosensitive detector means, for representing the intensity of the detected light by a data array;

data processing means, coupled to the means for representing the intensity of the detected light by a data array, for determining whether the test zones of the immunoassay test exhibit statistically significant results; and

output means, coupled to the data processing means, for outputting the results from the data processing means.

13. A screening device according to claim 12, wherein the data processing means includes filter means for filtering the data array prior to determining whether the test zones exhibit statistically significant results.

14. A method of screening an immunoassay test having discretely located test zones and a control zone interposed between background zones where the result of the test is indicated by the amount of a marker deposited in the control zones compared to the background and control zones, the method comprising the steps of:

illuminating the immunoassay test;

detecting the intensity of light reflected from the control zone, test zones and interposed background zones of the immunoassay test and converting the detected intensity to a data array;

processing the data to determine whether the data shows a substance level above a threshold; and

outputting the results of the processing.

15. A method of screening an immunoassay test according to claim 14, including the step of segmenting the data array into first, second and third pluralities of data, the first plurality of data corresponding to the control zone, the second plurality of data corresponding to the test zones, the third plurality of data corresponding to the background zones, and wherein the step of processing the data further comprises processing the first, second and third pluralities of data to determine whether the second plurality of data shows a substance level above a threshold set by reference to the first and second pluralities of data.

16. A method of screening an immunoassay test according to claim 14, wherein the immunoassay test is conducted on a saliva sample.

17. A method of screening an immunoassay test according to claim 14, wherein the outputted results are displayed on a liquid crystal device.

18. A screening device for interpreting an immunoassay test comprising:

illumination means for illuminating the immunoassay test;

means for detecting the intensity of the light from the illumination means which is reflected by the immunoassay test;

timing means, for producing a delay before commencement of the interpretation of the immunoassay test;

signal processing means, coupled to the timing means and coupled to the means for detecting the intensity of the light, for determining whether the immunoassay test shows statistically significant results after the delay has elapsed; and

output means, coupled to the signal processing means, for outputting the results from the signal processing means.

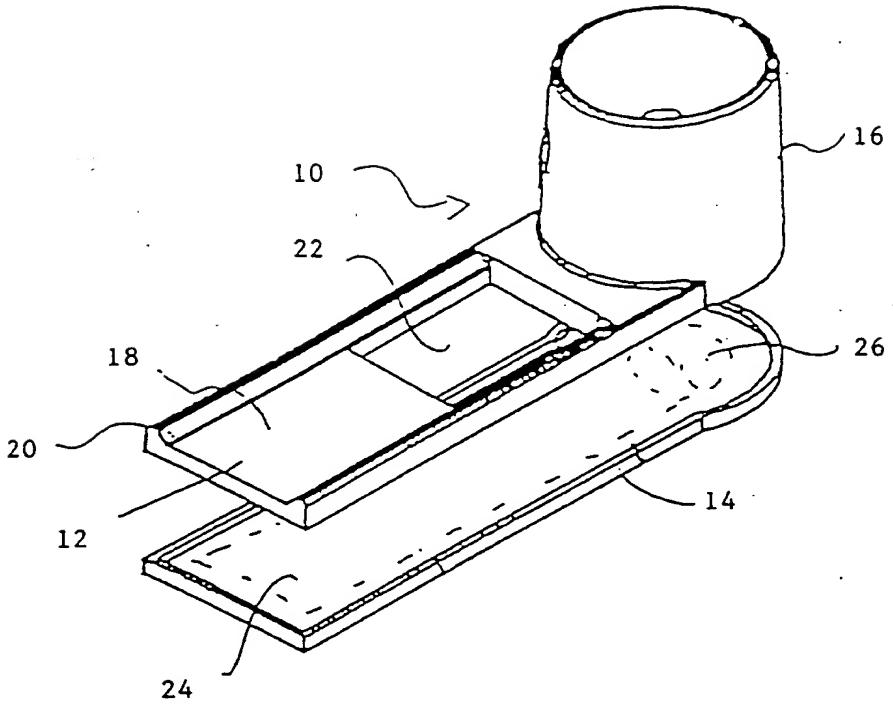


Fig 1

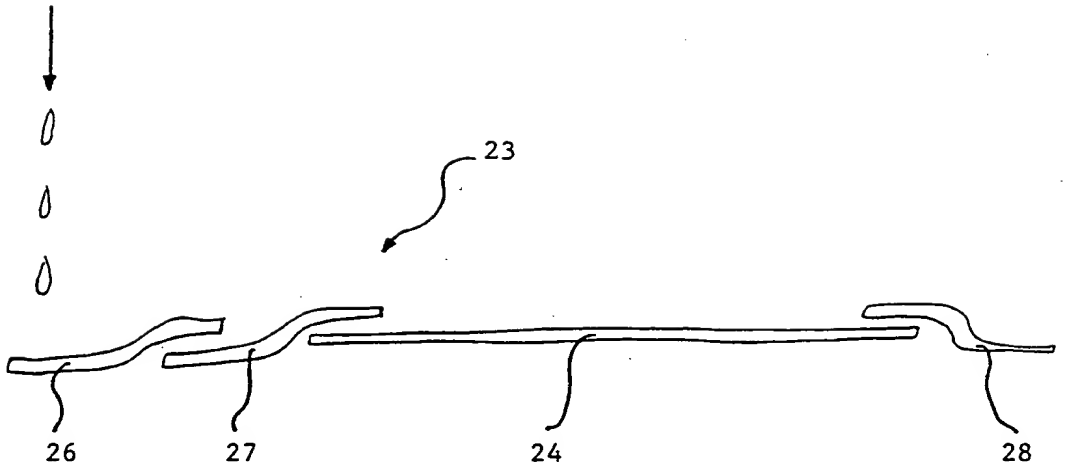


Fig 2

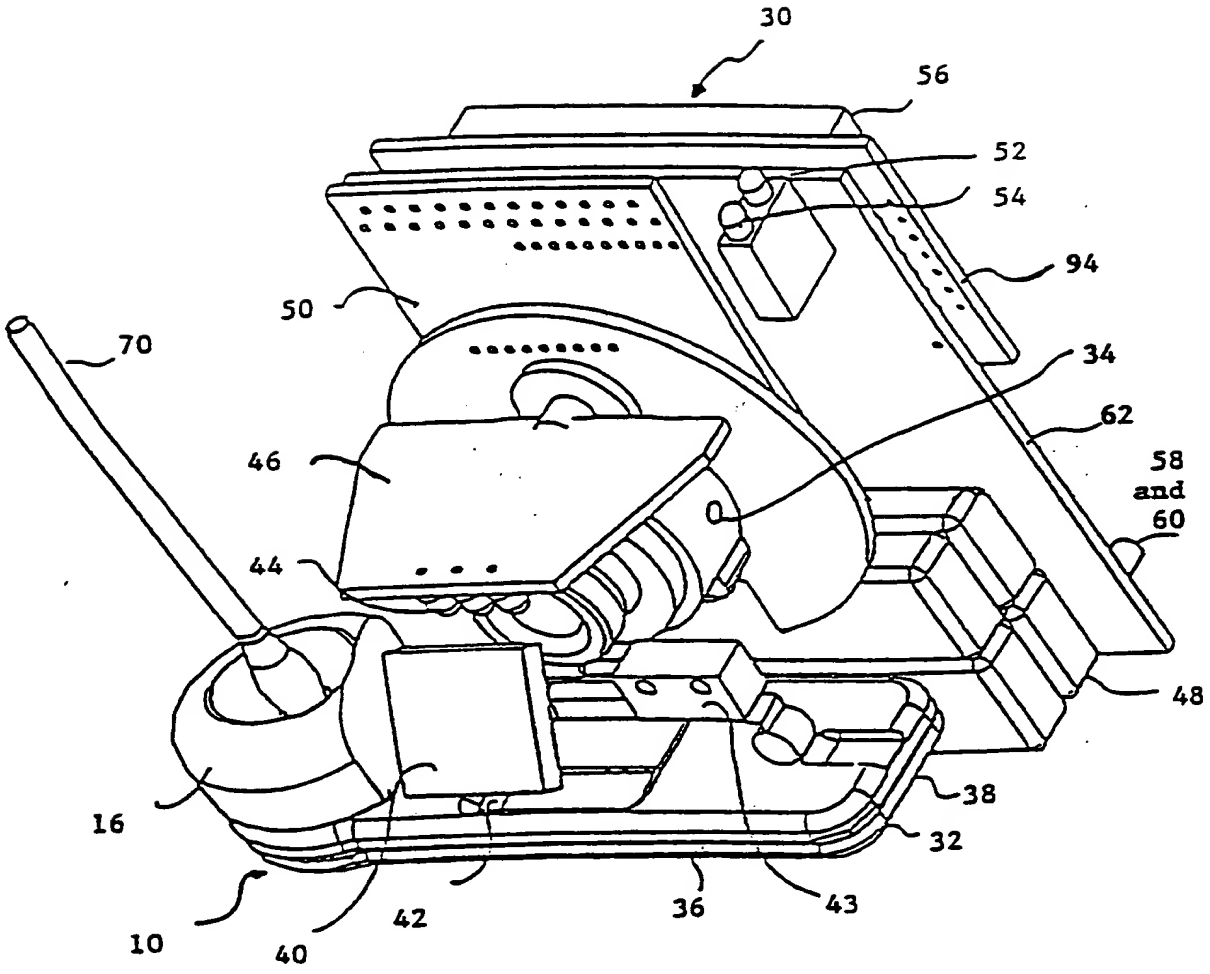


Fig 3

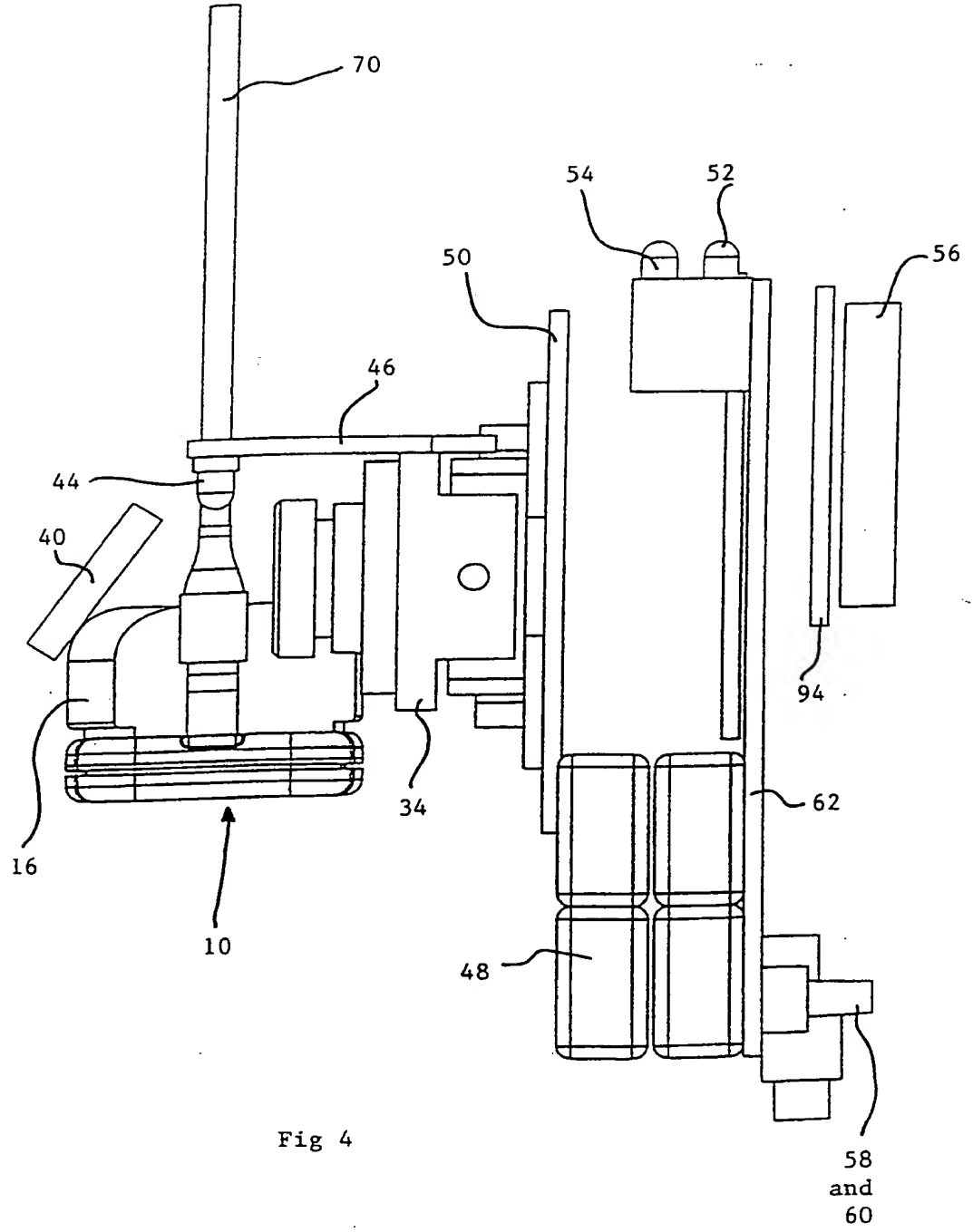


Fig 4

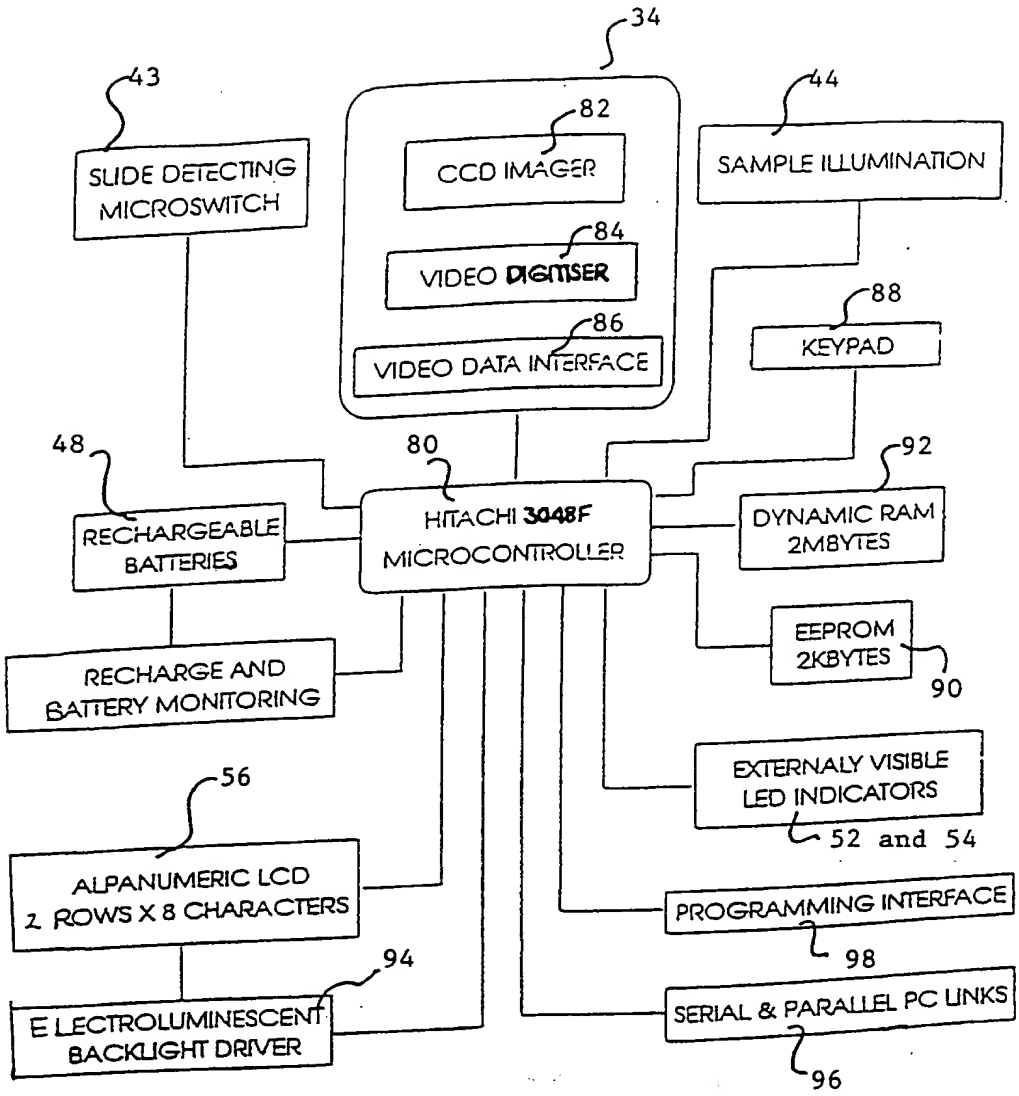

34
43
SLIDE DETECTING MICROSWITCH
82
CCD IMAGER
84
VIDEO DIGITISER
86
VIDEO DATA INTERFACE
44
SAMPLE ILLUMINATION
88
KEYPAD
48
RECHARGEABLE BATTERIES
80
HITACHI 3048F MICROCONTROLLER
92
DYNAMIC RAM 2MBYTES
EEPROM 2KBYTES
90
RECHARGE AND BATTERY MONITORING
EXTERNALY VISIBLE LED INDICATORS
52 and 54
56
ALPANUMERIC LCD 2 ROWS X 8 CHARACTERS
PROGRAMMING INTERFACE
98
94
ELECTROLUMINESCENT BACKLIGHT DRIVER
SERIAL & PARALLEL PC LINKS
96

Fig 5

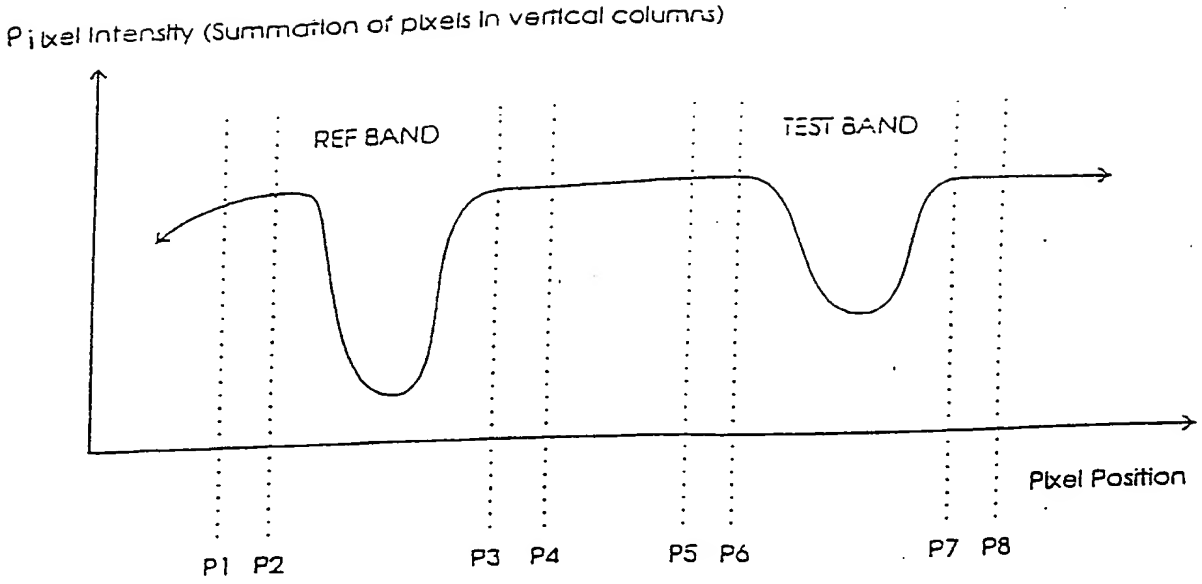

Pixel Intensity (Summation of pixels in vertical columns)
REF BAND
TEST BAND
Pixel Position
P1
P2
P3
P4
P5
P6
P7
P8

Fig 6

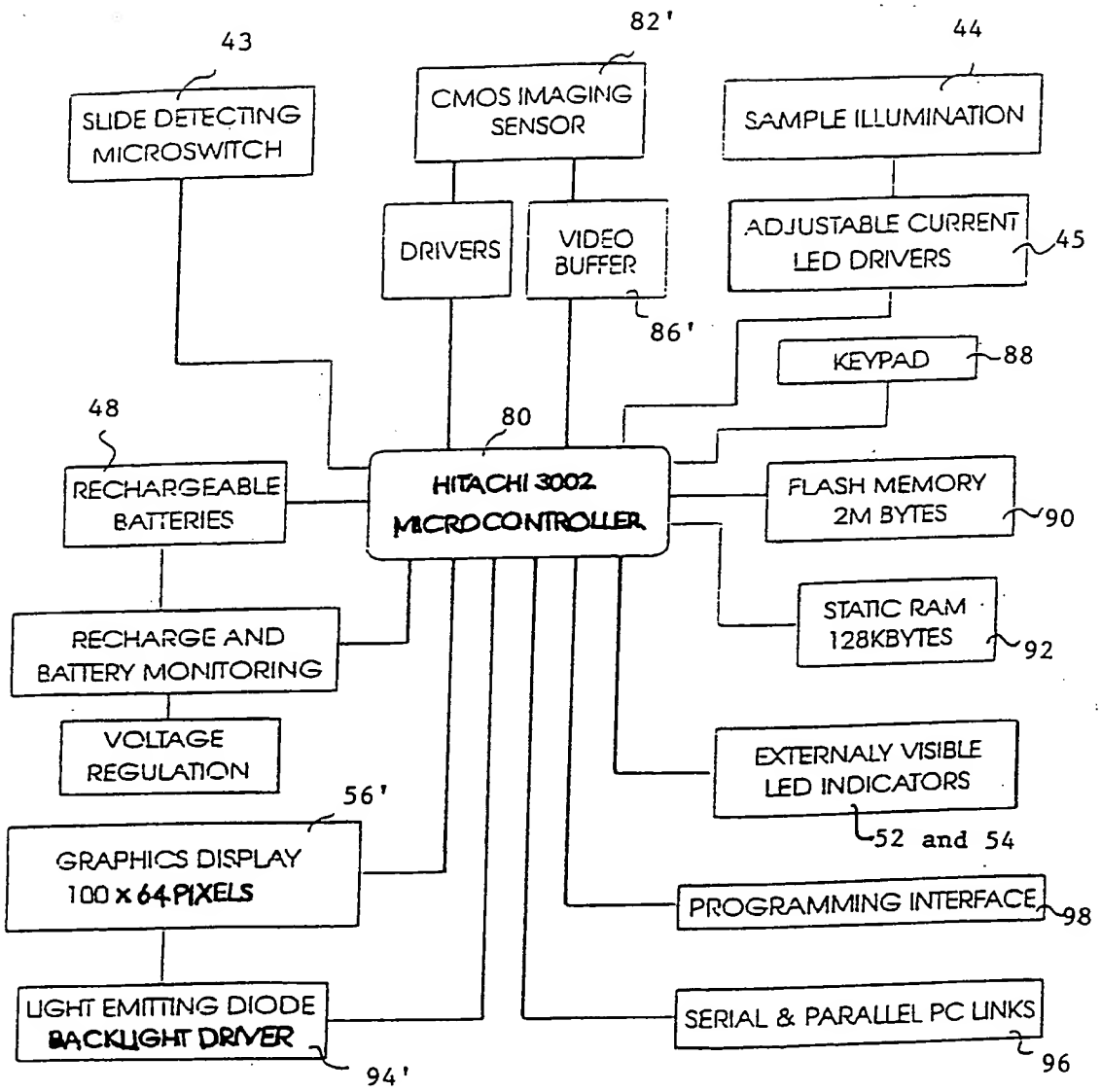

43
SLIDE DETECTING MICROSWITCH
82'
CMOS IMAGING SENSOR
44
SAMPLE ILLUMINATION
DRIVERS
VIDEO BUFFER
86'
ADJUSTABLE CURRENT LED DRIVERS
45
KEYPAD
88
48
RECHARGEABLE BATTERIES
80
HITACHI 3002 MICROCONTROLLER
FLASH MEMORY 2M BYTES
90
STATIC RAM 128KBYTES
92
RECHARGE AND BATTERY MONITORING
VOLTAGE REGULATION
EXTERNALY VISIBLE LED INDICATORS
52 and 54
56'
GRAPHICS DISPLAY 100 x 64 PIXELS
PROGRAMMING INTERFACE
98
LIGHT EMITTING DIODE BACKLIGHT DRIVER
94'
SERIAL & PARALLEL PC LINKS
96

Fig 7

INTERNATIONAL S. RCH REPORT

International / cation No CT/GB 99/02261

A. CLASSIFICATION OF SUBJECT MATTER

G01N33/53, G01N33/48

According to International Patent Classification (IPC) or to both national classification and IPC 7

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0073980 A1 (MERCK PATENTGESELLSCHAFT MIT BESCHRÄNKTER HAFTUNG) 16 March 1983, abstract, claims. ----	1,14, 15,18

☐ Further documents are listed in the continuation of box C.

☐ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

15 November 1999

Date of mailing of the international search report

23 DEC 1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer

SCHNASS e.h.

Form PCT/ISA/210 (second sheet) (July 1992)

ANHANG

zum internationalen Recherchenbericht über die internationale Patentanmeldung Nr.

ANNEX

to the International Search Report to the International Patent Application No.

ANNEXE

au rapport de recherche international relatif à la demande de brevet international n°

PCT/GB 99/02261 SAE 244177

In diesem Anhang sind die Mitglieder der Patentfamilien der im obengenannten internationalen Recherchenbericht angeführten Patentdokumente angegeben. Diese Angaben dienen nur zur Unterrichtung und erfolgen ohne Gewähr.

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The Office is in no way liable for these particulars which are given merely for the purpose of information.

La présente annexe indique les membres de la famille de brevets relatifs aux documents de brevets cités dans le rapport de recherche international visée ci-dessus. Les renseignements fournis sont donnés à titre indicatif et n'engagent pas la responsibilité de l'Office.

Im Recherchenbericht angeführtes Patentdokument Patent document cited in search report Document de brevet cité dans le rapport de recherche	Datum der Veröffentlichung Publication date Date de publication	Mitglied(er) der Patentfamilie Patent family member(s) Membre(s) de la famille de brevets	Datum der Veröffentlichung Publication date Date de publication
EP A1 73980	16-03-1983	DE A1 3135196	17-03-1983
		DE C0 3268128	06-02-1986
		EP B1 73980	27-12-1985
		JP A2 58055758	02-04-1983
		US A 4521522	04-06-1985